

### **REMARKS**

This is in response to the non-final Office Action mailed October 16, 2007.

Independent claim 1 and its dependent claims 2-3, 5-21 and 28-30, independent claim 22 and its dependent claim 23, and independent claim 24 and its dependent claims 26-27 are currently pending and at issue.

#### **Claim Rejection – 35 U.S.C. § 103(a)**

The Examiner has rejected claims 1-3, 5-20, 22-24 and 26-30 under 35 U.S.C. § 103(a) as being unpatentable over “Study: Calcium May Curb Weight Gain in Young Women” in ScienceDaily.com (“Science Daily”) in view of Tabbita, “The ‘Milk Mustache’ Campaign” (“Tabbita”). Applicants respectfully traverse because none of the cited or applied references, either alone or in combination, disclose, teach or suggest the methods of the cited claims.

Science Daily does not teach or suggest the claimed methods for inducing the consumption of calcium-containing products for weight loss in an individual in need thereof based on promoting or communicating to a consumer suffering from obesity that, in combination, consuming dietary calcium in an amount that is above suboptimal from a calcium-containing product and maintaining a restricted caloric diet below ad lib in a range that is about 200 kcal to about 2500 kcal per day has a beneficial effect selected from the group consisting of inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual.

Instead, the study discussed in Science Daily did not restrict subjects’ caloric intakes. The reference states that “[t]he women in the study . . . followed no specific diet . . . .” Paragraph 6. Nowhere does the reference disclose, teach or suggest a beneficial effect on body weight or body fat from the combination of maintaining a restricted caloric diet below ad lib and consuming dietary calcium in an amount that is above suboptimal from a calcium-containing product.

Moreover, the study discussed in Science Daily focused solely on women of normal weight (see paragraph 6). Science Daily does not disclose, teach or suggest that calcium has any effect in obese individuals. In fact, weight and body fat maintenance in the absence of caloric restriction does not predict, in any scientifically valid way, augmentation of weight and fat loss during energy restriction.

In addition, the study discussed in Science Daily focused exclusively on women aged 18-31, and it makes no mention of men. Furthermore, the study's author notes that the findings may not apply to women over 30, and states that "we cannot speculate on how it might affect women in other age groups" (see paragraph 15), let alone to men. In contrast, the claims at issue are unrestricted as to age or gender. Nowhere does the reference disclose, teach or suggest any effectiveness in men, or in women other than those aged 18-31. Indeed, weight maintenance becomes progressively more difficult with age. The endocrine environment is well known to affect weight, weight gain and ability to lose weight. A disclaimer that limits findings to young adult women would not be extrapolated to males or to older females, as the altered estrogen / androgen ratio would have unpredictable effects.

Furthermore, Science Daily is not an enabling disclosure. "A reference contains an 'enabling disclosure' if the public was in possession of the claimed invention before the date of invention. 'Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention.'" MPEP § 2121.01 (citing *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985)).

Science Daily is not an enabling disclosure for the claims at issue because it does not disclose a cause and effect relationship. Instead, the study discussed in Science Daily merely noted an association between intake of calcium from dairy sources and changes in body weight, and its authors were not even sure that calcium was the causative agent. Furthermore, the authors found other associations between nutrient intake and weight loss that are inconsistent with previous research in the field and conventional wisdom, and which the authors themselves characterized as "perplexing." These dubious associations call into question the validity of the study as a whole and cast doubt on any conclusions the authors drew based on their data. Thus, Science Daily does not disclose a relationship between calcium intake and weight effects in calorie-reduced individuals. The scientific evidence in Science Daily for the relationship is suspect at best. Given the weaknesses in the evidence and in light of federal regulations restricting merchants' ability to promote nutritional products without a demonstrated scientific basis, Science Daily does not enable

a method that would induce promoting dairy / calcium use. There is not adequate evidence for them to be permitted to make their claims.

The authors of the study discussed in Science Daily were unsure that calcium was the agent that caused the weight changes observed in the study. In a later-published peer-reviewed journal article which appears to be based on the same study, the authors, noting the observed ineffectiveness of non-dairy calcium at influencing body weight, stated that “[i]t is possible that another component of dairy products which was not analyzed in this study could be the factor which influences body weight.” Lin et al., "Dairy Calcium is Related to Changes in Body Composition During a Two-year Exercise Intervention in Young Women", *Journal of the American College of Nutrition*, 2000, 19(6), 754-760, p. 758. The authors of the journal article also state that “[a]nother possibility is that, if total dietary calcium increases, another nutrient decreases,” in which case the other nutrient, and not calcium, would be the causative agent. *Id.* In addition, the authors expected to find that increased calcium intake stimulated greater lipolysis among the subjects who exercise than among those who did not, but they found no evidence of increased lipolysis among the exercisers. Lin, p. 758. In light of the acknowledged weaknesses in the calcium / weight loss association noted above, this data casts further doubt on the authors’ conclusion that calcium caused the observed weight changes, a point the authors failed to note. Thus, in ways both acknowledged and overlooked by the study authors, their evidence for the apparent relationship between calcium and weight loss is shown to be largely speculative.

Furthermore, the authors’ attempt to elucidate a mechanistic rationale for their suggested association between calcium intake and weight changes further demonstrates how unsubstantiated their conclusions are. In the journal article, the authors discuss several calcium intervention studies that explore the role of calcium in adipocyte lipid metabolism to support their hypothesized mechanism for the calcium-weight change association. However, the authors are forced to acknowledge that “unfortunately,” the calcium intervention studies cannot even be compared to their study because, among other reasons, they have no basis for concluding that calcium in particular is the cause of the weight changes. Lin, p. 759.

Furthermore, the study data suggested several other associations that the authors chose to de-emphasize and that depart from prior research and conventional wisdom to such an extent that they

call into question the validity of the study as a whole. For example, the study found a positive correlation between vitamin A intake and changes in body weight, which the authors characterize as “perplexing” and inconsistent with other research in the area. Lin, p. 759. In addition, the study also noted a correlation between increased cholesterol intake and weight loss. They offer no explanation for this extremely counterintuitive result, other than to note that the result is “perplexing” and that “further investigation is warranted.”

In summary, a careful analysis of the published study based on the same data that formed the basis for the Science Daily article compels the following conclusions: 1) the authors focus on an alleged association between increased calcium intake and weight changes, but the data supporting the association is weak at best and some of the data actually refutes their conclusion; 2) the authors themselves acknowledge that they failed to exclude the possibility that a nutrient other than calcium was the causative agent, to the point that they admit they do not have a basis for comparing their study to calcium intervention studies; 3) their data supported other, more “perplexing” associations between nutrients and weight loss that depart from previous research and conventional wisdom that they call into question the validity of the study as a whole. Thus, Science Daily actually had little, if any, basis for the conclusion that “calcium may curb weight gain in young women.” Accordingly, because the assertions in Science Daily are speculative with little support in the data, such that the reference failed to put the public in possession of the claimed invention, Science Daily is not an enabling disclosure and thus is not a proper basis for a rejection.

In fact, a more supportable conclusion about the claims at issue is that, far from being obvious over the study discussed in Science Daily, the discoveries that gave rise to the claims at issue constitute unexpected results. The scientific literature is filled with associative data indicating that many nutrients are directly or inversely associated with obesity. Persons skilled in this field (a) do not infer causality from associative studies, and (b) would always look for an alternative explanation unless a plausible mechanism was presented to accompany the associative study. Indeed, a person of skill in the art, after evaluating the conclusions in the Science Daily study as well as the asserted bases for those conclusions, would likely decide that the conclusions are off-base, and would instead pursue other possible explanations for the observed weight loss.

Moreover, Applicants contend that Tabbita does not disclose, teach or suggest any of the elements of independent claims, nor cure the defects of Science Daily.

Tabbita discloses the promotion of milk for its beneficial effects on osteoporosis, not weight-related conditions, and the attempt of the dairy industry to market milk as being "cool", not as an agent producing weight-related benefits. Furthermore, Tabbita emphasizes the declining interest in the consumption of milk, attributing it to the perception that milk has a high fat content, and that when the fat content is removed, then the milk no longer contains beneficial vitamins and minerals. This statement would lead one away from the teaching of the present invention, which involves the use of dietary calcium or dairy, to directly induce weight loss or other weight-related effects.

Tabbita does not teach or suggest, methods for inducing the consumption of calcium-containing products or dairy for weight loss in an individual in need thereof based on promoting or communicating the benefits of calcium from the calcium containing products or dairy to directly induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue in the individual.

Therefore, Science Daily or Tabbita, either alone or in combination, do not disclose, teach or suggest the claimed invention as set forth in claims 1, 22, or 24. Nor do they teach or suggest the subject matter of dependent claims 2-3, 5-20, 23 and 26-30, which include additional limitations distinguishing them from the cited references.

Applicants respectfully request that this rejection be withdrawn.

The Examiner further rejects claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Science Daily in view of Tabbita and further in view of U.S. Patent No. 6,159,530, to Christiansen. Applicants traverse. Claim 21 depends from claim 1, and thus incorporates all of its elements. As discussed above, claims 1-3, 5-20, 22-24 and 26-30 are nonobvious over the combination of Science Daily and Tabbita. The addition of Christiansen does not cure the defects in the Science Daily / Tabbita combination. Christiansen refers in example 4 to a cereal containing a particular brand of calcium chelate, but does not describe communicating a trademark for a calcium-containing product for its weight-related effects as recited in the present claims. Accordingly, this rejection should be withdrawn.

Claims 1-3, 5-24 and 26-30 are patentable because none of the cited references or material disclose, teach or suggest the present invention. Applicants respectfully request that these rejections be withdrawn.

**Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-3, 5-24 and 26-30 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: Feb. 14, 2008

Respectfully submitted,

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